IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

IVETTE MERCADO,	)	
	)	
Plaintiff,	)	
	)	**No. 14 C 6699**
v.	)	
	)	**Judge Jorge L. Alonso**
BAYER HEALTHCARE PHARMACEUTICALS INC.,	)	
	)	
Defendants.	)	

MEMORANDUM OPINION AND ORDER

In this products liability action, defendant Bayer Healthcare Pharmaceuticals Inc. ("Bayer") moves to exclude the testimony of Gary S. Milzer, M.D., plaintiff Ivette Mercado's retained expert. For the following reasons, the motion is granted.

I. BACKGROUND

Plaintiff suffered an infection some time after her physician inserted a Mirena intrauterine device ("IUD"), a contraceptive device manufactured and sold by Bayer, into her uterine cavity on October 29, 2013. Mirena is a T-shaped polyethylene frame with a steroid reservoir that releases levonorgestrel, a prescription medication used as a contraceptive. On November 15, 2013, a couple of weeks after the Mirena was inserted, plaintiff returned to her physician complaining of lower abdominal pain, and the physician gave her antibiotics for possible pelvic inflammatory disease ("PID") or urinary tract infection. A urine culture revealed a Group A streptococcus infection. On December 3, 2013, plaintiff arrived in the emergency department of Advocate Lutheran General Hospital complaining of pelvic pain and illness. She was eventually admitted to the intensive care unit with possible toxic shock syndrome or septic shock. Although the physicians who treated her never definitively identified the cause of

plaintiff's infection, they removed her Mirena on December 7, 2013. Plaintiff later filed this suit, complaining that Bayer is strictly liable for failure to warn of the danger and risk of infection caused by a Mirena device, and that Bayer negligently misrepresented the risks of infection posed by insertion of a Mirena device.

II. LEGAL STANDARDS

"The admission of expert testimony is governed by Federal Rule of Evidence 702 and the principles outlined in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993); *see also Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 147-49 (1999) (extending application of *Daubert* factors to engineers and other non-scientific experts)." *Bielskis v. Louisville Ladder, Inc.*, 663 F.3d 887, 893 (7th Cir. 2011) (internal citations altered). Federal Rule of Evidence 702 provides as follows:

> A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:
> (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
> (b) the testimony is based on sufficient facts or data;
> (c) the testimony is the product of reliable principles and methods; and
> (d) the expert has reliably applied the principles and methods to the facts of the case.

The rule imposes "three basic prerequisites." *See Weinstein's Federal Evidence* § 702.02[3]. "Under Federal Rule of Evidence 702 and *Daubert*, the district court must . . . determine whether the witness is qualified; whether the expert's methodology is scientifically reliable; and whether the testimony will 'assist the trier of fact to understand the evidence or to determine a fact in issue.'" *Myers v. Ill. Cent. R.R. Co.*, 629 F.3d 639, 644 (7th Cir. 2010) (quoting *Ervin v. Johnson & Johnson, Inc.*, 492 F.3d 901, 904 (7th Cir. 2007)). In assessing reliability, the district court must ensure that the proffered expert testimony is "well-grounded in methods and procedures of science," and it should consider factors such as "(1) whether the [expert's] theory

can be and has been verified by the scientific method through testing; (2) whether the theory has been subjected to peer review; (3) the known or potential rate of error; and (4) the general acceptance of the theory in the scientific community." *Chapman v. Maytag Corp.*, 297 F.3d 682, 687 (7th Cir. 2002).

III. ANALYSIS

Defendant challenges the expert testimony of Dr. Milzer, a gynecologist who opines that "the *in-situ* Mirena IUD was the proximate cause" of pelvic inflammatory disease from an infection of Group A streptococcus bacteria that ultimately resulted in toxic shock syndrome in December 2013. (Mot. to Exclude, Ex. 2, Milzer Report at 4, ECF No. 70-4 at 10.) By saying that the Mirena caused the infection "*in situ*," Dr. Milzer means that it caused the infection while in place in the uterine cavity; he does not opine that the insertion of the Mirena caused the infection, apparently recognizing that the antibiotics plaintiff received on November 15, 2013, would have remedied such an infection. (*Id.*, Ex. 1, Milzer Dep., at 212:7-15, ECF No. 70-1.)

Defendant does not challenge Dr. Milzer's qualifications (although it says they "teeter on the edge of acceptability" (Reply Br. at 2, ECF No. 73)), but defendant does challenge his opinion on the grounds that it is not scientifically reliable and does not fit the facts of the case. First, defendant argues that Dr. Milzer's theory that a Mirena device can cause an infection *in situ*, separate and apart from its insertion, bears none of the indicia of reliability courts look for under *Daubert*: (a) no scientific data supports that theory; (b) the theory has not been published or peer-reviewed; (c) it has not garnered general acceptance in the medical community; (d) it has not been tested, nor is it easily testable, either in the context of this case or generally, because no culture samples were taken of plaintiff's Mirena after removal and, even if they had, it would be impossible to say whether the Mirena had been contaminated post-removal; and (e) Dr. Milzer admitted that he worked backwards from the fact of the infection to reach the conclusion that the

infection began with the IUD, a methodology that he did not dispute was inconsistent with general medical practice. Second, defendant argues that Dr. Milzer admitted that he relied on no published medical literature as support for his opinion; instead, he relied on "plaintiff lawyer websites" (Def.'s Mem. at 11, ECF No. 69) and other materials that he discovered by performing Google searches.[1] Finally, defendant argues that Dr. Milzer's opinion that the Mirena caused plaintiff's infection is unsupported by plaintiff's medical records or the testimony of the physicians who treated her because none of that evidence reveals precisely what caused plaintiff's infection.

Plaintiff responds that Dr. Milzer's opinion is scientifically reliable because cases of pelvic infections caused by the Mirena IUD are "not unheard of." (Resp. Br. at 6, ECF No. 71.) Plaintiff cites to Dr. Milzer's deposition, at which he estimated that approximately 10 such cases per million IUD insertions have been reported. (Mot. to Exclude, Ex. 1, Milzer Dep. at 118:25-119:20) Further, plaintiff argues, "Dr. Milzer testified that . . . an IUD can, on its own, increase the risk of pelvic infection." (Resp. Br. at 6 (citing Milzer Dep. at 98:15-99:3).)

Defendant is correct that Dr. Milzer cited no scientific data or published medical literature to support his opinion. No citations to any such sources appear anywhere either in his report (Mot. to Exclude, Ex. 2, ECF No. 70-4) or in his deposition testimony (*id.*, Ex. 1, ECF No. 70-1). True, Dr. Milzer testified at his deposition that there are 10 cases of pelvic inflammatory

[1] In his report, Dr. Milzer also opines that defendant's marketing and advertising violated FDA regulation, and defendant moves to bar these opinions as unfounded and improperly based on unscientific lawyer advertising and other unreliable Internet sources. Dr. Milzer apparently withdrew these opinions at his deposition, and plaintiff does not defend them in her response brief. It does not appear that plaintiff intends to offer Dr. Milzer's regulatory opinions in support of her claims, but the Court agrees with defendant that, if she does, she should be barred from doing so. Defendant persuasively argues that Dr. Milzer is not qualified to opine on regulatory compliance and has no proper technical basis for his opinions in that regard, and plaintiff makes no response. The proponent of expert testimony bears the burden of proving its admissibility, and where the proponent makes no substantive response to a *Daubert* challenge, the district court may decide to exclude the testimony within its sound discretion. *See Lewis v. CITGO Petroleum Corp.*, 561 F.3d 698, 705-06 (7th Cir. 2009). Defendant's motion to exclude Dr. Milzer's regulatory opinions is granted.

disease per million IUD insertions, but he went on to explain that he believed he learned this statistic from reading the portion of the expert report of defense expert Dr. Dana Gossett, M.D., in which Dr. Gossett discussed the European Active Surveillance Study, or "EURAS," a study with which Dr. Milzer was previously unfamiliar. (*Id.* at 109:20-110:9, 118:25-119:20.) In her report, Dr. Gossett explained that the EURAS researchers were primarily analyzing the rate of uterine perforation among IUD users, and they also analyzed the rate of unintended pregnancy among IUD users. (Gossett Report re: Mirena Litigation,[2] ECF No. 70-1, at 132-33.) Nowhere in her discussion of EURAS does Dr. Gossett say anything about any data collected by the EURAS researchers concerning rates of pelvic infections or pelvic inflammatory disease among IUD users. The 10-cases-per-million figure Dr. Milzer thought he recalled does not appear there. Neither Dr. Gossett's discussion of EURAS nor any other portion of her reports[3] provides any support for Dr. Milzer's opinion that an IUD *in situ*, as opposed to an IUD insertion, can cause an infection that would not otherwise occur.

As for Dr. Milzer's testimony that "an IUD can, on its own, increase the risk of pelvic infection," (*see* Resp. Br. at 6 (citing Milzer Dep. at 98:15-99:3)), at most this passage merely restates Dr. Milzer's opinion that an IUD can somehow cause an infection by itself; it sheds no light on whether the opinion is based on any scientific data or methodology.

Plaintiff also argues that Dr. Milzer's opinion is scientifically reliable because it is consistent with the testimony of two of plaintiff's treating physicians, Dr. Courtney J. Steller and

[2] The record contains two reports rendered by Dr. Gossett: one report on the risks and benefits of Mirena and other IUDs generally, and another report addressing the facts of plaintiff's case specifically.

[3] Although Dr. Gossett's discussion of EURAS appears in her general Mirena litigation report, plaintiff also cites a portion of Dr. Gossett's separate report on plaintiff's case, in which Dr. Gossett explains that "pelvic infection with IUD is a warned-about risk." (Gossett Report re: Ivette Mercado v. Bayer, ECF No. 70-1, at 145-46.) But this portion ties the risk to insertion, so it does not support Dr. Milzer's theory.

Dr. Robert J. Citronberg, both of whom, plaintiff says, recognized that an IUD can cause an infection. But plaintiff mischaracterizes the testimony of both physicians.

Plaintiff claims that Dr. Steller testified that it is "highly unlikely but possible" that plaintiff's Mirena IUD caused her infection. (*See* Mot. to Exclude, Ex. 10, Steller Dep., at 75:22-23, ECF No. 70-12.) But it is not clear that this testimony, viewed in its full context, supports Dr. Milzer's theory that a Mirena *in situ*, as opposed to the insertion of a Mirena, can cause an infection. In the same line of questioning, just four answers before the testimony plaintiff cites, Dr. Steller testified that she removed plaintiff's Mirena during the treatment of the infection because:

> it used to be standard of care that if someone did develop pelvic inflammatory disease after an IUD ***insertion***, that you did remove the IUD because that was thought to cause the pelvic inflammatory disease. Now more you just treat it with antibiotics and you can leave the IUD in place.

(*Id.* at 74:18-24 (emphasis added)). Dr. Steller appeared to believe that the infection was tied to the IUD insertion, if anything, not to the IUD *in situ*. Further, if, as Dr. Steller explained, practitioners now generally leave an IUD in place while treating a pelvic infection, it suggests that they believe that the IUD itself is generally not the cause of the infection. Dr. Steller's testimony undermines Dr. Milzer's theory more than it supports it.

As for Dr. Citronberg, when asked if it was possible that the Mirena caused plaintiff's infection, he testified that he recalled "rare reports of IUDs causing toxic shock syndrome . . . . So is it possible? Yes, but it's not a classic association." (*Id.*, Ex. 11, Citronberg Dep., at 68:7-11, ECF No. 70-13). This may provide lukewarm corroboration of Dr. Milzer's theory, but like Dr. Steller, Dr. Citronberg may have been talking about IUD insertion rather than IUD *in situ*. In other testimony he seemed to cast doubt on the idea that the Mirena, by itself, can cause a Group A streptococcus infection and ultimately toxic shock syndrome. He recognized that "bacteria

that [were] part of the normal vaginal flora" could "adhere to foreign [devices] that are inside" the human body and cause an intrauterine infection (*id.* at 65:15-66:4), but he also testified that Group A streptococcus is not a normal part of the vaginal flora[4] (*id.* at 66:5-7); rather, it is a pathogen that "has to be introduced somehow. So, you know, there is nothing magical in just having the device. The bacteria [have] to come from somewhere" (*id.* at 66:8-13).

This matter of the bacteria having to "come from somewhere" presents a serious problem for Dr. Milzer's theory that the Mirena caused a Group A streptococcus infection because there is no evidence in the record to suggest that a Mirena *in situ* can somehow cause or facilitate the introduction of harmful bacteria, as even Dr. Milzer seemed to recognize at his deposition:

> Q: [U]nder your theory, [the Mirena] goes into [plaintiff's] uterus, causes an infection, and that gets treated [in November] . . . [a]nd you're saying that goes away, and then she has a second infection before the December admission?
> A: Yeah.
> . . .
> Q: Where—how did the Group A strep get into her uterus at some point after November 15, but before December 3?
> A: Good question.
> . . .
> Q: It's just, under your scenario, your theory, the IUD is an innocent bystander. It happens to be there. A pathogen gets in the environment somehow, unrelated to it, and it becomes a nidus for the infection, right?
> A: Yeah. Well, working backwards . . . I think you can track it back to how the . . . strep infection was caused by the IUD, just by working backwards.
> Q: Well, but that's a methodology that isn't consistent with general medical practice, is it?
> A: It's an explanation here.
> . . .
> Q: Well, but, again, . . . [i]f the Mirena IUD in its insertion is not responsible for the Group A strep getting into her uterus, it just happens to be there. . . . Because it is a foreign body, it could have been a penny . . . . It could be anything. The pathogen is going to gloam [*sic*] onto the foreign body, right? That's a natural process, right?
> A: Yeah . . . .
> Q: All right. And . . . does your theory include the Mirena IUD being in situ, . . . and somehow it spontaneously creates a Group A strep organism?
> A: Seemingly, that's what happened.

[4] Dr. Milzer ultimately admitted that he agreed with Dr. Citronberg on this point. (Milzer Dep. at 211:14-212:6.)

> Q: Do you have any medical or scientific evidence that that type of thing can happen?
> A: Well, it fits with the history and what happened.
> Q: I'm not talking about . . . Ms. Mercado. I'm [asking] is there any one piece of medical or scientific data that shows that the IUD, the Mirena IUD, can just spontaneously create a pathogen like Group A strep?
> A: No.

(*Id.*, Ex. 1, Milzer Dep., at 212:16-20; 213:15-214:4; 214:12-24; 215:14-216:4.) It is clear that Dr. Milzer had no scientific basis for linking the mere presence of the Mirena to the infection, and indeed he had no factual basis for linking the Mirena to the infection other than that the Mirena was inserted near the time of the infection. He simply concluded from the fact that plaintiff had recently had a Mirena inserted that the Mirena must have caused her pelvic infection. (*See id.* at 143:4-7 ("I mean, common things are common. This woman had an IUD infection from Mirena, and I – I don't see that there's any way to cloud that up. I mean, I think it's fairly straightforward."), 199:12-18 ("I would say given a cascade of events that have happened up until now, this patient has pelvic inflammatory disease. And with all the sequela that followed, I think it pretty much confirms that this patient had pelvic inflammatory disease from the IUD, from . . . an *in situ* Mirena IUD")). But when asked whether there is any "medical or scientific support in the published medical literature" for the theory that "there is an increased risk of infection with an IUD unrelated to its insertion," Dr. Milzer responded, "Not that I specifically know of. . . . I don't have any medical literature backing . . . right now." (*Id.* at 99:23-100:15.) When confronted with data showing (as Dr. Steller had suggested at her deposition) that outcomes for women who retain their IUDs while they receive treatment for pelvic infections are typically no worse than outcomes for women who remove their IUDs while receiving such treatment, suggesting that the IUD itself has little or nothing to do with the

infection, Dr. Milzer cited no countervailing data, responding only, "I'm just thinking about our patient here, Ivette Mercado." (*Id.* at 130:24-25.)

Under these circumstances, the inference Dr. Milzer draws is not scientifically reliable. It is evidently based on nothing more than the fact that plaintiff suffered a pelvic infection a few weeks after the insertion of her Mirena IUD. Dr. Milzer admits that his conclusion is based on no scientific or medical data suggesting that a Mirena may cause an infection merely by existing in a woman's uterine cavity a few weeks after its insertion, rather than by becoming contaminated during insertion. His conclusion is, at best, no better than a layperson's inference that the Mirena must have had something to do with the infections she suffered, considering the temporal proximity of the insertion of the Mirena and the infections, and such an inference is insufficiently scientific to pass muster under *Daubert* and Rule 702. *See Porter v. Whitehall Labs., Inc.*, 9 F.3d 607, 611, 615-16 (7th Cir. 1993) (affirming district court's exclusion of expert testimony when expert's causation theory was based on nothing more than a "temporal relationship" between the purported cause and effect). Expert testimony must be scientifically reliable, and Dr. Milzer's opinion is not based on science; it is based on speculation. *See Bielskis*, 663 F.3d at 895-96 (affirming district court's exclusion of expert's causation theory where expert's "sources of information" were "nothing more than his own speculation" and expert performed no testing); *see also Myers*, 629 F.3d at 645 (affirming district court's exclusion of the causation opinions of plaintiff's treating physicians because "[o]ther than common sense, there was no methodology to their etiology. . . . In other words, the basis for their opinions is properly characterized as a hunch or an informed guess. And the 'courtroom is not the place for scientific guesswork, even of the inspired sort.'" (quoting *Rosen v. Ciba-Geigy Corp.*, 78 F.3d 316, 319 (7th Cir. 1996))). At best, Dr. Milzer's opinion is the sort of "scientific

guesswork" that the Seventh Circuit has held to fall short of the standard set by Rule 702 and *Daubert*. The Court agrees with defendant that Dr. Milzer's opinion is not admissible as expert testimony because it is not scientifically reliable.

CONCLUSION

For the reasons set forth above, the Court grants defendant's motion to exclude Dr. Milzer's expert testimony [68]. A status hearing is set for May 18, 2017 at 9:30 a.m.

SO ORDERED.

ENTERED: April 25, 2017

HON. JORGE L. ALONSO
United States District Judge